

1 Adopt 17 Cal. Code of Regs. section 100001 to read:

2 **§ 100001. Definitions for Working Group Conflict of Interest Provisions.**

3 The following definitions apply to the conflict of interest regulations contained in this
4 Chapter:

5 (a) “Applicant” includes investigators, the project director(s) and the applicant entity or
6 entities. Each campus of a statewide university is considered to be a separate institution.

7 (b) “CIRM” is the California Institute for Regenerative Medicine.

8 (c) “Facilities Working Group” refers to the Scientific and Medical Facilities Working
9 Group.

10 (d) “Grant” means a grant, loan or guarantee.

11 (e) “Grantee” means a recipient of a grant from the institute. Each campus of a
12 statewide university shall be considered as a separate and individual grantee institution.

13 (f) “Grants Review Working Group” refers to the Scientific and Medical Research
14 Funding Working Group.

15 (g) “Member” is a non-ICOC individual appointed to serve as a voting member on a
16 working group.

17 (h) “Principal Investigator” is an individual designated by the grantee to direct the
18 project or activity being supported by the grant.

19 (i) “Project Director” is an individual designated by the grantee to direct the project or
20 activity being supported by the grant.

21 (j) “Standards Working Group” refers to the Scientific and Medical Accountability
22 Standards Working Group

- 1 (k). “Working Group” means any of three advisory bodies to the Independent Citizens’
2 Oversight Committee (“ICOC”), the governing body of the CIRM.
3 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
4 Health and Safety Code.
5 Reference: Sections 125290.50, 125290.55, 125290.60, 125290.65, 125292.10, subds. (i) and (j),
6 Health and Safety Code.

1 Adopt 17 Cal. Code of Regs. section 100002 to read:

2 **§ 100002. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical**
3 **Accountability Standards Working Group.**

4 (a) Prohibitions: Non-ICOC Members of the Standards Working Group are precluded
5 from deriving direct financial benefit from the CIRM through grants, loans or contracts and from
6 acting as a Principal Investigator on any CIRM-funded grant. Senior academic officers
7 (including, but not limited to, chancellors, presidents of institutions, deans, chairs of
8 departments, executive officers of research institutions, and other similar positions), who, as part
9 of their responsibilities, oversee and advise researchers in their institution or who sign off on
10 grants, loans or contracts shall not be deemed to have a conflict of interest under this regulation.

11 (b) Disclosure: A non-ICOC working group member has a financial interest in and must
12 disclose confidentially and under penalty of perjury the following:

13 (1) All California-based academic or non-profit research institutions from which
14 Standard Working Group members, their spouses, or others with whom a member has a common
15 financial interest, receive current income of \$5,000 or more;

16 (2) All biotechnology and pharmaceutical companies from which members, their
17 spouses, or others with whom a member has a common financial interest, receive current income
18 or other benefit or investments of \$5,000 or more; and

19 (3) All real property interests in California of \$5,000 or more (including real
20 estate interests and interests in intellectual property such as patents and copyrights) held by
21 members, their spouses, or others with whom a member has a common financial interest.

1 (c) Disqualification: A conflict of interest exists when there is a financial or other
2 interest that significantly impairs the individual's objectivity or that creates an unfair advantage
3 for any person, institution or company. A non-ICOC member has a conflict of interest when any
4 financial interest identified in subdivision (b) of this regulation is the subject of a decision before
5 the working group. A member of the Working Group who has a real or apparent conflict of
6 interest with respect to a decision may not participate in the decision and must leave the room
7 when that decision is discussed. In exceptional cases, the President of the CIRM may decide that
8 the need for special expertise of a member outweighs any possible bias posed by a real or
9 apparent conflict of interest. Under these circumstances, the CIRM staff shall publicly disclose
10 the working group member's interest before the meeting and the working group member shall be
11 permitted to participate in the discussion but will not be permitted to vote on the matter.

12 (d) Record-Keeping: All financial disclosure documents shall be kept confidential by the
13 CIRM staff and preserved for purposes of review by the State Auditor or another independent
14 auditor and any other audit as required by law. Records of the working group indicating those
15 members who participated in or voted on particular recommendations shall be maintained by the
16 CIRM staff. If the CIRM or an auditor discovers a violation of these conflict of interest
17 provisions, a report will be made to the Legislature along with a review of corrective actions
18 taken by the CIRM to prevent future occurrences.

19 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
20 Health and Safety Code.

21 Reference: Sections 125290.50, subd (e), 125290.55, Health and Safety Code.

1 Adopt 17 Cal. Code of Regs. section 100003 to read:

2 **§ 100003. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical**

3 **Research Funding Working Group.**

4 (a) Prohibition: Except as provided otherwise in this regulation, a Grants Review
5 Working Group member may not participate in a decision of the working group in which the
6 individual has a conflict of interest. A conflict of interest exists when a non-ICOC Grants
7 Review Working Group member has a real or apparent interest in the outcome of an application
8 such that the member is in a position to gain financially, professionally or personally from either
9 a positive or negative evaluation of the grant proposal.

10 (b) “Financial: Conflict of Interest - Defined: A non-ICOC member has a financial
11 conflict of interest if:

12 (1) The member, his or her spouse, or any other person with whom the member has a
13 common financial interest, is an employee of either the institution or the Principal Investigator
14 on an application.

15 (2) The member, his or her spouse, or any other person with whom the member has a
16 common financial interest, is under active consideration for a faculty or administrative position
17 at an applicant institution.

18 (3) A member, his or her spouse, or any other person with whom the member has a
19 common financial interest, stands to receive a financial benefit of any amount from an
20 application under review.

21 (4) A member, his or her spouse, or any other person with whom the member has a
22 common financial interest, has received or could receive a financial benefit of any type from an

1 applicant institution or organization unrelated to the proposal, of over \$5,000 per year. This total
2 includes honoraria, fees, stock and other benefits. It also includes current stock holdings, equity
3 interest, intellectual property or real property interest, but does not include diversified mutual
4 funds.

5 (c) “Professional” Conflict of Interest - Defined: A non-ICOC member has a professional
6 conflict of interest if:

7 (1) A person listed on the grant application as Principal Investigator or someone who
8 receives salary from the grant is a professional associate, such as a former student or post-
9 doctoral fellow, or someone with whom the member has co-authored a publication within the last
10 three years.

11 (2) The member and a primary member of the applicant’s research team are engaged in,
12 or are planning to be engaged in, collaboration.

13 (3) An applicant is someone with whom the member has had long-standing scientific
14 differences or disagreements that are known to the professional community and could be
15 perceived as affecting the member’s objectivity.

16 (d) “Personal” Conflict of Interest - Defined: A non-ICOC member has a personal
17 conflict of interest if:

18 (1) A close family member or close personal friend is an applicant.

19 (2) An applicant is someone with whom the member has had long-standing personal
20 differences.

21 (e) Disclosure: A non-ICOC working group member shall disclose confidentially and
22 under penalty of perjury the following financial interests:

1 (1) All California-based academic or non profit research institutions from which
2 members, their spouses, or others with whom the member has a common financial interest,
3 receives income or other benefit of \$5,000 or more.

4 (2) All publicly-held biotechnology and pharmaceutical companies from which
5 members, their spouses, or others with whom a member has a common financial interest,
6 receives current income or other benefit, or holds an investment, of \$5,000 or more.

7 (3) All privately held biotechnology companies in which reviewers, their spouses,
8 or others with whom a member has a common financial interest, has an equity interest.

9 (4) Real property interests in California held by members, their spouses, or others
10 with whom a member has a common financial interest.

11 (f) Disqualification: A non-ICOC member is required to report to the CIRM staff any
12 conflict of interest of which he or she is aware, including, but not limited to, those described in
13 subdivisions (b) through (d) of this regulation. Any member of the Grants Review Working
14 Group who has a real or apparent conflict of interest with respect to an application may not
15 review or vote on the application and must leave the room when that application is discussed. In
16 exceptional cases, the President of the CIRM may decide that the need for special expertise of
17 the reviewer outweighs any possible bias posed by a real or apparent conflict of interest. Under
18 these circumstances, the CIRM staff shall publicly disclose the working group member's interest
19 before the meeting and the working group member shall be permitted to participate in the
20 discussion but will not be permitted to vote on the application or participate in the scientific
21 scoring.

1 (g) All non-ICOC members must sign a pre-review statement indicating any possible
2 conflicts of interest that they have, and must also sign a post-review statement that they did not
3 participate in the discussion or review of any application for which they might have a conflict of
4 interest, or shall indicate permission to participate was granted by the President pursuant to
5 subdivision (e) of this regulation.

6 (h) Record-Keeping: All financial disclosure documents shall be kept confidential by the
7 CIRM staff and preserved for purposes of review by the State Auditor or another independent
8 auditor and any other audit as required by law. Records of the working group indicating those
9 members who participated in or voted on particular recommendations shall be maintained by the
10 CIRM staff.

11 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
12 Health and Safety Code.

13 Reference: Sections 125290.50, subd. (e), 125290.60, Health and Safety Code.

1 Adopt 17 Cal. Code of Regs. section 100004 to read:

2 **§ 100004. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical**

3 **Facilities Working Group.**

4 (a) Prohibitions: Except as provided otherwise in this regulation, a Facilities Working
5 Group member may not participate in a decision of the working group in which the individual
6 has a conflict of interest. Non-ICOC members serving on the Facilities Working Group may not
7 receive compensation from any construction or development entity providing specialized
8 services for medical research facilities. Non-ICOC members may not provide real estate facilities
9 brokerage services for any applicant for a facilities grant, or for any entity that receives funding
10 from the Facilities Working Group, and shall not receive compensation from any recipient of
11 CIRM funding grants.

12 (b) Conflict of Interest Protections: A conflict of interest exists when a non-ICOC
13 Working Group member has a real or apparent interest in the outcome of an application such that
14 the member is in a position to gain financially or professionally from either a positive or negative
15 evaluation of the grant proposal.

16 (c) “Financial” Conflict of Interest - Defined: A non-ICOC member has a financial
17 conflict of interest if:

18 (1) The member, his or her spouse, or any other person with whom the member has a
19 common financial interest, is an employee of any construction, real estate or development entity
20 on an application.

21 (2) The member, his or her spouse, or any other person with whom the member has a
22 common financial interest, is under active consideration for employment at an applicant entity.

1 (3) A member, his or her spouse, or any other person with whom the member has a
2 common financial interest, stands to receive a financial benefit of any amount from an
3 application under review.

4 (4) A member, his or her spouse, or any other person with whom the member has a
5 common financial interest, has received or could receive a financial benefit of any type from an
6 applicant institution or organization unrelated to the proposal, of over \$5,000 per year. This total
7 includes honoraria, fees, stock and other benefits. It also includes current stock holdings, equity
8 interest, intellectual property or real property interest, but does not include diversified mutual
9 funds.

10 (d) “Professional” Conflict of Interest - Defined: A non-ICOC member has a professional
11 conflict of interest if the reviewer and a project director or manager of an application are
12 engaged in, or are planning to be engaged in, a joint project.

13 (e) Disclosure: A non-ICOC working group member shall disclose confidentially and
14 under penalty of perjury the following financial interests:

15 (1) All California-based academic or non-profit research institutions from which
16 members, their spouses, or others with whom a member has a common financial interest,
17 receives current income or other benefit of \$5,000 or more.

18 (2) All construction, real estate or development firms from which members, their
19 spouses, or others with whom a member has a common financial interest, receives current
20 income or other benefit, or holds an investment, of \$5,000 or more.

21 (3) All real property interests in California held by members, their spouses, or others with
22 whom a review has a common financial interest.

1 (f) Disqualification: A non-ICOC member is required to report to the CIRM staff member
2 any conflict of interest of which he or she is aware, including, but not limited to, those described
3 in subdivisions (c) and (d) of this regulation. Any member of the Facilities Working Group who
4 has a real or apparent conflict of interest with respect to an application may not review or vote on
5 the application and must leave the room when that application is discussed. In exceptional cases,
6 the President of the CIRM may decide that the need for special expertise of the reviewer
7 outweighs any possible bias posed by a real or apparent conflict of interest. Under these
8 circumstances, the CIRM staff shall publicly disclose the working group member's interest
9 before the meeting and the working group member shall be permitted to participate in the
10 discussion but will not be permitted to vote on the application.

11 (g) All members reviewing grants must sign a pre-review statement indicating any
12 possible conflicts of interest that they have, and must also sign a post-review statement that they
13 did not participate in the discussion or review of any application for which they might have a
14 conflict of interest, or shall indicate permission to participate was granted by the President
15 pursuant to subdivision (e) of this regulation.

16 (h) Record-Keeping: All financial disclosure documents shall be kept confidential by the
17 CIRM staff and preserved for purposes of audit as provided for in Health and Safety code
18 Section 125290.30 and any other audit as required by law. Records of the working group
19 indicating those members who participated in or voted on particular recommendations shall be
20 maintained by the CIRM staff.

21 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
22 Health and Safety Code.

1 Reference: Sections 125290.50, subd. (e), 125290.65, Health and Safety Code.